UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/171,928	10/05/1998	NORIO INOMATA	47259-0336	8658

55694 7590 08/28/2006

DRINKER BIDDLE & REATH (DC)
1500 K STREET, N.W.
SUITE 1100
WASHINGTON, DC 20005-1209

EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/171,928	GLENN, J. BRANDAL	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/05/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-11,21 and 30-35* is/are pending in the application.

4a) Of the above claim(s) *8-11 and 30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/04/05 09/06/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 8-11, 21,30-35 are pending.

Response to restriction requirement filed 06/05/2006 is acknowledged. Applicant elected with traverse, Group III, claims 33-35. Applicant argues that there is no burden of search. As explained in the restriction requirement, there is a lack of unity between Groups II and III because the common technical feature for these groups is treatment of cardiac hypertrophy using natriuretic peptide receptor activator. The prominent difference between the methods is that while method of Group II specifies that the effect occurs without causing diuretic and hypotensive effect, method of Group III is inclusive of such mechanism. Note that this distinction was recognized as critical in the course of prosecution of this case. Treatment of cardiac hypertrophy using natriuretic peptide receptor activator is not the contribution over the prior art because it is suggested by references teaching treatment of cardiac hypertrophy using natriuretic peptide receptor activators. The restriction requirement is maintained. Claims 8-11, 30-32 are withdrawn from consideration as being directed to non-elected Groups.

Claims 33-35 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 33, 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 33,34 recites the limitation "the natriuretic peptide". There is insufficient antecedent basis for this limitation in the claim as claim 33 does not recite natriuretic peptide.

Claim Objections

3. Claim 34 is objected to because of the following informalities: The claim uses term "arterial" natriuretic peptide. It seems that specification addresses the peptide as "atrial" rather than "arterial" – see specification, p. 5, line 23, for example. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 103.

4. Claims 33,34 are rejected under 35 U.S.C. 103(a) as obvious over Blaine as evidenced by Cao et al. or Espiner anf further in view of Tilley et al. (Recent advances in studies on cardiac structure and metabolism, (1975) 10, 641-53).

The claims are directed to method for decreasing heart weight comprising administering a substance that i) acts on guanylyl cyclase A natriuretic receptor and ii) accelerates production of cyclic guanosine monophosphate. The patients to be treated

are suffering from cardiac hypertrophy which produces pulmonary congestion. Dependent claim 34 specifies that the a substance that acts on guanylyl cyclase A natriuretic receptor and accelerates production of cyclic guanosine monophosphate is natriuretic peptide.

Blaine teaches method of treatment of cardiac hypertrophy using atrial natriuretic peptide (ANP) and fragments thereof. See abstract, summary, col. 3, lines 11-20, and claims 1-8. In particular, the treatment reverses cardiac hypertrophy and reduces heart weight – see Example 11, col. 4, lines 23-41. Thus, the reference teaches method of reducing heart weight after cardiac hypertrophy. With regard to the term "a substance that acts on guanylyl cyclase A natriuretic receptor and accelerates production of cyclic guanosine monophosphate", as discussed in the course of preceding prosecution, natriuretic peptide acts on guanylyl cyclase A natriuretic receptor and thus accelerates production of cyclic guanosine monophosphate. It is well known that ANP, as well as its analogs stimulate guanylate cyclase A and production of cGMP. Thus, Cao et al demonstrates that the hypertrophy-reducing effect of the natriuretic peptides is due to their interaction with guanylyl cyclase A natriuretic peptide receptor and is further mediated by formation of cGMP (p. 231, and p. 233, second paragraph. Further, see Espiner teaching that natriuretic peptides is due to their interaction with guanylyl cyclase

A natriuretic peptide receptor and is further mediated by formation of cGMP(p. 205, last paragraph). 1

Blaine does not teach that cardiac hypertrophy has to be a result of chronic cardiac hypertrophy which cardiac hypertrophy produces pulmonary congestion.

The Blaine reference is not limited to any particular origin of cardiac hypertrophy but rather teaches that any disorders of altered vascular resistance and/or of electrolyte disbalance can be treated col. 3, lines 11-20. As cardiac hypertrophy results initiates onset of heart failure (see discussion of knowledge in the art, specification, p. 1, last paragraph) and the latter manifests in pulmonary congestion (see, for example, Tilley et al. (Recent advances in studies on cardiac structure and metabolism, (1975) 10, 641-53) as discussed in Office action of 08/19/2003, p.4) it would be obvious to one skilled in the art that the method of Blaine generally addressing cardiac hypertrophy will be applicable to "chronic cardiac hypertrophy which produces pulmonary congestion" as instantly claimed.

5. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Claims 33,34 are rejected under 35 U.S.C. 103(a) as obvious over Blaine as evidenced by Cao

---

1 With respect to comments of the applicant about applicability of Espiner reference, as addressed before, although the date of the "Espiner" reference is later than the priority date of the instant application, the reference is a review describing studies preceding the instant application; the reference is used merely to demonstrate well known mechanisms of action.

et al. or Espiner anf further in view of Tilley et al. as applied to claims 33,34 above, and further in view of Salito et al (Circullation, 76:, 115-124, 1987).

The references as applied as above. With regard to claim 35, BNP is functional equivalent of ANP – see Salito reference, for example, as discussed in applicant's response of 0906/2005, p. 6).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb
08/10/2006